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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/582,404      06/23/00      YAMASHITA      N      19941A-00030

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HM22/0813

EXAMINER

PRYOR, A

ART UNIT

PAPER NUMBER

1616

DATE MAILED:

08/13/01

**Please find below and/or attached an Office communication concerning this application or proceeding.**

~~Commissioner of Patents and Trademarks~~

# Office Action Summary

Application No.

09/582,404

Applicant(s)

Yamashita et al

Examiner

Alton Pryor

Art Unit

1616

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on Jun 23, 2000.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-16 is/are pending in the application.
- 4a) Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-16 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claims \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119

- 13) ☒ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☒ All b) ☐ Some\* c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

## Attachment(s)

- 15) ☐ Notice of References Cited (PTO-892) 18) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 19) ☐ Notice of Informal Patent Application (PTO-152)
- 17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). \_\_\_\_\_ 20) ☐ Other: \_\_\_\_\_

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***Claim Rejection under 35 U.S.C. 112, 1st paragraph***

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claims 1-16 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for prostanoic acid derivatives specified or listed in the specification, does not reasonably provide enablement for prostanoic acid derivatives not listed in the specification. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make/use the invention commensurate in scope with these claims. Examiner suggests that applicant combine claims 1 and 4.

***Claim Rejection under 35 U.S.C. 112, 2nd paragraph***

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 1-16 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.
5. The term "prostanoic acid derivative" in claims 1-16 is a relative term which renders the claim indefinite. The term "prostanoic acid derivative" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary

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skill in the art would not be reasonably apprised of the scope of the invention. See 35 U.S.C. 112, 1st paragraph .

*Claim Rejections under 35 U.S.C. 103(a)*

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. Claims 1-13,16 are rejected under 35 U.S.C. 103(a) as being unpatentable over JP 02262519; 1025/90.

JP '519 discloses an agent comprising a prostaglandin I2 derivative as an ammonium salt. See abstract. JP '519 does not teach the instant ratio, specific ammonium compounds and specific PG I2 compound. It would have been obvious to one having ordinary skill in the art at the time the invention was made to make the agent comprising the instant ammonium and PGI2 compounds. One would have been motivated to do this because all ammonium compounds and PGI2 compounds would have similar structure and similar activity. The optimal ratio of ionic compound to PGI2 compound would have been determined through routine experimentation.

8. Claims 1-7,11-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over JP 04356422; 12/10/92.

JP '422 discloses an composition comprising a prostaglandin I2 derivative plus sodium oleate. See abstract. JP '422 does not teach the instant ratio, specific ammonium compounds and

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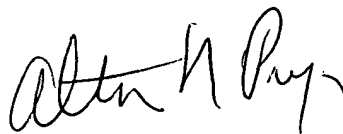
specific PG I2 compound. It would have been obvious to one having ordinary skill in the art at the time the invention was made to make the derivative comprising the instant ammonium and PGI2 compounds. One would have been motivated to do this because JP '422 suggests the derivative. The optimal ratio of ionic compound to PGI2 compound would have been determined through routine experimentation.

*Telephonic Inquiry*

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alton Pryor whose telephone number is (703) 308-4691. The examiner can normally be reached on Monday through Friday from 8:00 a.m. to 4:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jose Dees, can be reached on (703) 308-4628. The fax phone number for this Group is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-1235.

A handwritten signature in black ink, appearing to read 'Alton H. Pryor', with a stylized flourish at the end.

Alton Pryor

Patent Examiner, AU 1616

8/10/01